

### **Remarks/Arguments**

Claims 1-3, 5-7, 9 and 13-15 were originally pending. Claims 4, 8, 10-12 and 16-70 were previously canceled. Claims 6 and 9 have now been canceled. Claims 1-3, 5, 7, and 13-15 are now pending. Claim 1 has been amended. No new matter has been added by way of amendment. Applicants ask that all pending claims be examined and allowed.

### **Changes to the Specification**

The Examiner has suggested that the Applicants amend the first line of the specification to include the provisional application 60/117,281. The Applicants have updated the application priority information accordingly.

### **Previous Rejections Under 35 U.S.C. §102(b)**

The Examiner previously rejected claims 1-4, 8, 9, and 13-15 under 35 U.S.C. 102(b) as being anticipated by Fabian *et al.* (J. Cell Biochem., 1993, 17G: 153-160, IDS). The Examiner argued that Fabian *et al.* teaches a method of needle aspiration that would include ductal fluid (secretions) and ductal epithelial cells. The Applicants have amended claim 1 to include the limitation of obtaining a sample by nipple aspiration of the milk ducts or by ductal lavage of at least one breast milk duct. Both ductal lavage and nipple aspiration are noninvasive methods of obtaining ductal fluid from a patient.

Since Fabian *et al.* does not teach or suggest obtaining a sample by nipple aspiration of the milk ducts or by ductal lavage of at least one breast milk duct, Fabian *et al.* cannot anticipate the claim 1 of the present invention as amended. For this reason, the Applicant's respectfully submit that previous rejections under 35 U.S.C. 102(b) should not be applied to the present claims as amended.

The Examiner previously rejected claims 1-6, 8, and 13-15 under 35 U.S.C. 102(b) as being anticipated by Sauter *et al.* (British J. Cancer., 1997, 76(4): 494-501, IDS). The Examiner argued that Sauter *et al.* teaches a non-invasive method for the early detection of breast cancer comprising collecting nipple aspirate fluid from a patient, cytologically analyzing the fluid (e.g. computerized image analysis of nipple aspirate fluid epithelial cells), and evaluating the promising cancer markers, wherein the patients were categorized by their risk for breast cancer as having no risk factors, a first degree relative with breast cancer, a history of curative treatment for ductal carcinoma in situ (DCIS), or invasive breast cancer, precancerous mastopathy, atypical hyperplasia (AH) or lobular carcinoma in situ (LCIS) or recently diagnosed invasive cancer or the breast.

The Applicants have amended claim 1 to include the limitation of obtaining a sample by nipple aspiration of the milk ducts or by ductal lavage of at least one breast milk duct and examining the ductal fluid sample to determine the presence of an estrogen receptor on precancerous or cancerous ductal epithelial cells, wherein asymptomatic patients determined to have the presence of an estrogen receptor on precancerous or cancerous ductal epithelial cells are considered likely to benefit from administration of an estrogen activity modulator for risk reduction or therapeutic treatment of breast cancer.

Since Sauter *et al.* does not teach or suggest examining a ductal fluid sample to determine the presence of an estrogen receptor on precancerous or cancerous ductal epithelial cells, wherein asymptomatic patients determined to have the presence of an estrogen receptor on precancerous or cancerous ductal epithelial cells are considered likely to benefit from administration of an estrogen activity modulator for risk reduction or therapeutic treatment of breast cancer, Sauter *et al.* cannot anticipate the claim 1 of the present invention as amended. For this reason, the Applicant's respectfully submit that previous rejections under 35 U.S.C. 102(b), should not be applied to the present claims as amended.

The Examiner previously rejected claims 1-4, 6-8, and 13-15 under 35 U.S.C. 102(b) as being anticipated by JAMA (May 7, 1973, 224 (6): 823-827). The Examiner argued that the JAMA reference discloses using the claimed method; Dr. Sartorius found carcinomas in the breast of patients who appeared asymptomatic. The Applicants have amended claim 1 to include the limitation of obtaining a sample by nipple aspiration of the milk ducts or by ductal lavage of at least one breast milk duct and examining the ductal fluid sample to determine the presence of an estrogen receptor on precancerous or cancerous ductal epithelial cells, wherein asymptomatic patients determined to have the presence of an estrogen receptor on precancerous or cancerous ductal epithelial cells are considered likely to benefit from administration of an estrogen activity modulator for risk reduction or therapeutic treatment of breast cancer. Since the JAMA reference does not teach or suggest examining a ductal fluid sample to determine the presence of an estrogen receptor on precancerous or cancerous ductal epithelial cells, wherein asymptomatic patients determined to have the presence of an estrogen receptor on precancerous or cancerous ductal epithelial cells are considered likely to benefit from administration of an estrogen activity

modulator for risk reduction or therapeutic treatment of breast cancer, the JAMA reference cannot anticipate the claim 1 of the present invention as amended. For this reason, the Applicant's submit that the rejections under 35 U.S.C. 102(b), should not be applied to the present claims as amended.

### **The Double Patenting Rejections**

The Examiner has previously rejected claims 1-3, 5-7 and 15 on the ground of non-statutory obviousness-type double patenting as being unpatentable over claims 1, 9, 13, 15, and 19-21 of USP 6,610,484. In the Applicant's response filed on December 7, 2006, the Applicants noted that the current Application 10/608,225 and USP 6,610,484 were, at the time the invention of Application 10/608,225 was made, owned by Cytoc Corporation. What the Applicants failed to make clear is that both the current Application 10/608,225 and USP 6,610,484 claim priority from the same Provisional Application 60/117,281 filed January 26, 1999. For this reason, the Applicants respectfully submit that the non-statutory obviousness-type double patenting rejection should not be applied to the present claims as amended.

The Examiner has previously rejected claims 1, 6, 7 and 15 on the ground of non-statutory obviousness-type double patenting as being unpatentable over claims 1, 2, 11, 13, and 22 of USP 6,642,009. In the Applicant's response filed on December 7, 2006, the Applicants noted that the current Application 10/608,225 and USP 6,642,009 were, at the time the invention of Application 10/608,225 was made, owned by Cytoc Corporation. What the Applicants failed to make clear is that the current Application 10/608,225 claims priority from Provisional Application 60/117,281 filed January 26, 1999 while USP 6,642,009 claims priority from

Provisional Application 60/166,100 filed November 17, 1999. For this reason, the Applicants respectfully submit that the non-statutory obviousness-type double patenting rejection should not be applied to the present claims as amended.

**REMARKS**

Entry of this amendment prior to examination is requested. Applicant asks that all claims be examined and allowed. Early notice to this effect is solicited.

It is not believed that extensions of time or fees for net addition of claims are required, beyond those that may otherwise be provided for in documents accompanying this paper. However, in the event that additional extensions of time are necessary to allow consideration of this paper, such extensions are hereby petitioned under 37 CFR § 1.136(a), and any fee required therefore (including fees for net addition of claims) is hereby authorized to be charged to Deposit Account No. 502855 referencing attorney docket number 12.003011 DIV.

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